

510(k) Summary of Safety and Effectiveness

**510(k) Submitter:**

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K961195

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**Names of Device:**

Trade Name:	Chem-Chex STAT
Common Name:	Assayed chemistry control
Classification Name:	Multi-analyte control (§862.1660)
Classification Number:	75JJY

**Predicate Device:**

i-STAT control (K934641) manufactured for i-STAT Corp.

**Description:** Chem-Chex STAT is a suspension of stabilized human red blood cells in an aqueous buffered medium. Manufactured in two clinically significant levels, it is packaged in dropper tip polyethylene vials containing 2.0 mL volumes. Closures are injection molded polypropylene screw-top caps. Vials are packaged in polystyrene jars.

**Intended Use:** Chem-Chex STAT is intended to be used for verifying the accuracy of i-STAT chemistry analyzers used with 6+ test cartridges. Chem-Chex STAT is assayed for Na<sup>+</sup>, Cl<sup>-</sup>, K<sup>+</sup>, BUN, Hgb, Hct, and Glucose.

**Comparison with Predicate Device:** Like the i-STAT Control, Chem-Chex STAT is intended to enable the user to verify satisfactory performance of the i-STAT analyzer and cartridge system. Both devices are liquid controls containing sodium, chloride, potassium, blood urea nitrogen, and glucose.

Unlike the i-STAT Control, Chem-Chex STAT is an assayed control. This provides the user a complete positive procedural control. In addition, Chem-Chex STAT contains red blood cells and is assayed for hemoglobin and hematocrit. It is not assayed for PCO<sub>2</sub>, PO<sub>2</sub>, pH, or ionized calcium.

**Discussion of Tests and Test Results:** Three studies of Chem-Chex STAT were conducted: I) lot to lot reproducibility and comparison with whole blood; II) within lot reproducibility; and III) long term and open vial stability. Study results showed CVA to be consistently reproducible, substantially equivalent to the predicate product, and stable for the entire product dating

**Conclusions Drawn from Tests:** Study results show Chem-Chex STAT to be consistently reproducible, substantially equivalent to the predicate product, and stable for the entire product dating. Chem-Chex STAT is a safe and effective product which fulfills its intended use when used as instructed in the product package insert.